UNITED STATES PATENT AND TRADEMARK OFFICE

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EXAMINER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

	Application No.	Applicant(s)
	10/813,604	PALMIERI ET AL.
Office Action Summary	Examiner	Art Unit	
	P. Kathryn Wright	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2010*.

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-47* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

Status of the Claims

1.   This action is in response to papers filed May 21, 2010 in which claims 39, 41-43

were amended. The amendments have been thoroughly reviewed and entered.   Any

previous objection/ rejection not repeated herein has been withdrawn.

Applicant's arguments have been thoroughly reviewed but are deemed moot in

view of the amendments, withdrawn rejections and new grounds for rejection. New

grounds for rejection, necessitated by the amendments, are discussed.

Claims 27-47 are under prosecution.

Claim Rejections - 35 USC § 102

2.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3.   Claims 27-45 remain rejected under 35 U.S.C. 102(b) as being anticipated by

Choperena et al. (US Patent no. 5,380,487), hereinafter "Choperena".

Choperena teaches a multipath access system for use in an automated

immunoassay analyzer. The Choperena system comprises a transport device having

means for holding a plurality of vessels 52 having a plurality of vessel holding members

(i.e., carriers 64 and fingers 68). It is expected that the transport device moves a

plurality of vessels along one or more continuous loops (e.g., along belt 54) via at least

one motor (i.e., mechanism for moving the vessel holding means).

Choperena teaches at least two transfer stations 80, 120, each comprising a "means for moving" or transfer shuttle for moving the vessel in and out of the vessel holding means (e.g., carrier fingers 68 on belt 54). As to claims 40-41, the transfer shuttle includes a horizontal support (i.e., floor 104) and at least two projecting members (i.e., fingers 103) that project from the horizontal support. The projecting members 103 are spaced far enough apart to accommodate the vessel. The transfer shuttle is positioned to slide perpendicular to a portion of the transport device (belt 54 and carrier 64). That is, the fingers 103 of Choperena slip between the fingers 68 of belt 54 in a direction perpendicular to a portion of belt 54 (see for example col. 13, line 10-col. 16, line 4 and Figs. 4-8).

As to claims 41-43, Choperena teaches the transfer shuttle (floor 104 and fingers 103) is positioned so that upon sliding in a direction perpendicular to a portion of the transport device (e.g., carrier 64 and fingers 68), the first projecting member of the transfer shuttle contacts a first test vessel 52 held in a vessel holder 64 and pushes the first test vessel 52' from the transport device 64 into the transfer station 80, while a second adjacent projecting member 130 of the transfer shuttle contacts a second test vessel 52 held in the transfer station 80 and pushes the second test vessel 52 out of the transfer station into wash loop 101 of the wash station (see for example Figs. 4-5).

The system of Choperena also includes a programmable controller system programmed to determine the individual path (e.g., predetermined path 58) along the continuous loop for each of the vessels, wherein the determination of each path is based on resource requirement (e.g., types of reagents added, duration of incubation, dilution, agitation, number of wash cycles in wash station path 101) associated with

each vessel. See entire document, for example col. 5, line 33-col. 6, line 51, col. 17, line

56- col. 18, line 8 and col. 19, line 69-col. 20, line 31.   The paths determined by the

controller do not depend on the order in which the controller receives the information.

That is, the Choperena analyzer controller does not follow a "first-in-first-out" pattern of

entering and processing the test (see entire document, for example col. 5, line 26 to col.

6, line 64).

As to claim 31, the system of Choperena includes a second transport device that,

like the first transport device, can house separate read station 130. The second

incubation chamber will necessarily include all the elements of the first incubation

chamber, including the transfer station positioned to slide in a direction perpendicular to

the horizontal direction of the transport porter device belt 54 and shown in detail in Figs.

4 to 8 (see col. 41, lines 41-52). The second transfer station necessarily includes a

second "means for moving" (or transfer shuttle) for moving the vessel in and out of the

second vessel holding means 64 (see for example col. 14, lines 13 et seq.)

Regarding claim 32, the multi-path system of Choperena also includes at least

one delivery station 72 for adding a vessel to the transport device at a specified vessel

holding member 64 of the plurality of vessel holding members (see for example col. 12,

line 17 et seq.)

With respect to claim 33, the Choperena system includes pipetting station 40 for

adding one or more reagents to a vessel 52 positioned in a vessel holding member 64

of the transport device (see col. 10, line 3 et seq.)

As to claims 34-35 and 44, Choperena also teaches wash station 100 for washing test vessels positioned therein. The wash station 100 is combined with (attached to) the transfer stations 80, 120 (see Figs. 4-8.)

With respect to claims 36-37, Choperena teaches stationary (fixed) agitating means (spinning means not shown) positioned adjacent the transport device at a location where the vessels in the holding members contact the agitating member (see for example col. 16, lines 18-30).

Regarding claim 38, Choperena teaches the means for moving the vessel holding means 64 (i.e., via motor) is adapted to move the vessels in a clock-wise direction around the loop 54 (see Figs. 4-8).

As to claim 45, the Choperena controller determines an optimized individual path along a first continuous loop 54 for each of a plurality of samples based on a resource requirement (e.g., duration of incubation, dilution, agitation, number of wash cycles in wash station path 101) for each sample.

Claim Rejections - 35 USC § 103

4.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5.   The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

   1.   Determining the scope and contents of the prior art.
   2.   Ascertaining the differences between the prior art and the claims at issue.
   3.   Resolving the level of ordinary skill in the pertinent art.
   4.   Considering objective evidence present in the application indicating
         obviousness or nonobviousness.

6.   This application currently names joint inventors. In considering patentability of

the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g)

prior art under 35 U.S.C. 103(a).

7.   Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Choperena.

      As discussed above, Choperena teaches a means for moving the vessel holding

means 64 (i.e., via motor) adapted to move the vessels in a clock-wise direction around

the loop 54. Choperena also teaches the programmable controller is able to move and

transfer the vessel between the continuous loops 54 to wash station loop 100 and/or

read station loop 130. The Choperena controller determines an individual path along a

first continuous loop 54 for each of a plurality of samples based on a resource

requirement (e.g., duration of incubation, dilution, agitation, number of wash cycles in

wash station path 101) for each sample and transferring the vessel from the first

continuous loop 54 to a second continuous loop (i.e., wash station loop 100 or read

station loop 130). Choperena teaches optimizing the path determined for each sample

such that samples having identical resource requirements travel an equal distance around the first continuous loop (see for example col. 5, lines 33- col. 6, line 20). Choperena does not specifically recite herein for at least one sample the equal distance comprises the sum of a first distance and a second distance, wherein the first distance is traveled in a clockwise direction around the first continuous loop, wherein the second distance is traveled in a counterclockwise direction around the first continuous loop. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to move the motor of the first continuous loop (belt 54) clockwise and then counterclockwise so as to achieve the necessary incubation time before transporting to the second continuous loop (e.g., wash station loop 100 or read station loop 130).

Response to Arguments

8.   Applicant's arguments filed May 21, 2010 have been fully considered but they are not persuasive. In response to the previous rejection of claims 27-45 under 35 U.S.C. 102(b) as being anticipated by Choperena, applicant argues "Choperena does not disclose a multipath access system for use in an automated immunoassay analyzer, comprising a transfer a transfer shuttle [sic], positioned to slide in a direction perpendicular to a portion of the transport device, for moving vessels to and from the vessel holders, and a programmable controller, programmed to determine an individual path along the continuous loop for each of a plurality of vessels, where each vessel has a resource requirement". Applicant argues, as stated at col. 6, lines 17 - 24, each slot of the Choperena analyzer is equal to the first indexing time of the incubator belt, and thus a vessel can be transferred to the wash wheel only at the beginning of the indexing

cycle of the incubator. Because the processing cycle is fixed, the scheduler matches

analyte tests and assay resources within the fixed cycle. This is because each of the

vessels on belt 54 and each of the vessels on wash wheel 102 moves in

synchronization because the belt 54 intersects the wash wheel 102 in single position-

by-position increments. Applicant further assert, as disclosed at col. 13, lines 1 - 6,

reactions vessels are transported along a predetermined path and at predetermined

positions along that path the reaction vessels will be acted upon by the wash station

and/or the read station. In contrast, the claims of the present disclosure require that the

vessels proceed on an individual path based on the resource requirement associated

with each vessel, which is enabled by the "means for moving vessels" as claimed. In

addition, the claimed programmable controller utilizes information about the resource

requirements for each individual vessel to determine the individual path. Therefore,

applicant concludes Choperena does not anticipate the claims of the present application

at least because there is no programmable controller as claimed, and therefore an

individual path cannot be determined for each vessel.

The examiner respectfully disagrees. First, is it noted that applicant makes no

specific argument regarding the transfer shuttle. Second, the cited portions in

Choperena (i.e., col. 6, lines 17-24 and col. 13, lines 1-6), do not appear to correspond

of what applicant is describing. Nevertheless, the examiner maintains that the system

of Choperena does, in fact, teach a programmable controller system programmed to

determine the individual path (e.g., predetermined path 58) along the continuous loop

for each of the vessels, wherein the determination of each path is based on resource

requirement (e.g., types of reagents added, duration of incubation, dilution, agitation,

number of wash cycles in wash station path 101) associated with each vessel. See

entire document, for example col. 5, line 33-col. 6, line 51, col. 17, line 56- col. 18, line 8

and col. 19, line 69-col. 20, line 31.   The paths determined by the controller do not

depend on the order in which the controller receives the information. That is, the

Choperena analyzer controller does not follow a "first-in-first-out" pattern of entering and

processing the test (see entire document, for example col. 5, line 26 to col. 6, line 64).

The determination of each path for each vessel is based on the types of reagents

added, duration of incubation, dilution, agitation, number of wash cycles in wash station

path 101) associated with each vessel. See for example col. 6, lines 3-20, wherein

Choperena teaches "...each assay resource has a predetermined fixed operation

window within the fixed processing cycle. Resultingly, the control logic for one assay

resource can rely on predetermined timing of other dependent and independent assay

resources. Therefore, analyte tests having variable protocols and that are processed by

moving reaction vessels in different chronologies can be interleaved if their assay

resource requirements do not conflict, (i.e., analyte tests with shorter processing time

can be entered after those with longer processing times and the shorter analyte test can

finish first.) This can be done because the means of transporting reaction vessels

containing assay constituents can present reaction vessels to the necessary assay

resources in whatever order is required, regardless of entry order. In a preferred

embodiment an optimizing routine is used by the analyzer control means for increased

performance and throughput." (Emphasis added.) Thus, Choperena clearly teaches a

programmable controller, programmed to determine an individual path along the

continuous loop for each of the reaction vessels, based on a resource requirement (e.g.,

types of reagents added, duration of incubation, dilution, agitation, number of wash

cycles in wash station path 101) associated with each vessel.

Conclusion

9.   No claims are allowed.

10.   Applicant's amendment necessitated the new ground(s) of rejection presented in

this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

11.   Any inquiry concerning this communication or earlier communications from the

examiner should be directed to P. Kathryn Wright whose telephone number is (571)272-

2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM,

EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for

the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

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For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. Kathryn Wright/
Primary Examiner, Art Unit 1797